

**REMARKS**

Claims 1, 2, 6-12, 17-20, 24-29, 32, and 33 were pending in the present application. Claims 1, 2, 6-10, 17-20, 24-29, and 32 have been canceled herein without prejudice to their presentation in another application. Claim 11 has been amended herein, support for which can be found throughout the specification and at, for example, page 9, lines 27-29, and at page 10, lines 22-32 of the specification. New claims 34-41 have been added herein, support for which can be found throughout the specification and at, for example, claims 14-17 and 19 as published in the International application. No new matter has been added. Upon entry of the present amendment, claims 11, 12, and 33-41 will be pending.

**I. The Claimed Invention is Novel**

Claims 19, 20, 24-29 and 32 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,713,059 (hereinafter the “Kende reference”). Although Applicants disagree with the reasons for rejection, solely to advance prosecution of the present application, claims 19, 20, 24-29 and 32 have been canceled herein without prejudice to their presentation in another application. Thus, the present rejection is moot.

**II. The Claimed Invention is Not Obvious**

Claims 1, 2, 6-12, 17-20, 24-29, and 32 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the Kende reference in view of McCafferty et al., Nature, 1990, 348, 552-554 (hereinafter the “McCafferty reference”). Claims 1, 2, 6-10, 17-20, 24-29, and 32 have been canceled herein and thus the rejection is moot with respect to these claims. Applicants disagree with the rejection as it is applied to claims 11 and 12.

Claim 11 has been amended as described above to specify that the homoserine lactone molecules are conjugated to a first carrier molecule and further screened against the homoserine lactone molecule conjugated to a second, different carrier molecule. It has been submitted previously that the antibodies of the Kende reference are generated in animals following multiple immunizations with an immunogenic conjugate of a lactone signalling molecule. This approach relies upon generation of antibodies *in vivo* by the immune system of the animal and is the basis

of vaccine development. The present application, in contrast, teaches how to generate human antibodies that are specific for the free form (i.e., soluble, non-conjugated form) of a signalling molecule.

When a homoserine lactone signalling molecule is conjugated to the first carrier molecule to produce a first conjugate, screening using the naïve human phage display library identifies antibodies that recognize the free form of the signalling molecule and also antibodies that recognize the first conjugate, thereby generating the enriched library. The second screening step involves screening the enriched library against the signalling molecule conjugated to a second, different carrier molecule. This eliminates many of the antibodies that recognize the first conjugate and also promotes the identification of antibodies that recognize the free form of the signalling molecule, as the only common epitopes between the two conjugate molecules are on the signalling molecule. In this manner, the selection of antibodies for the free form of homoserine lactone molecules can be promoted, in stark contrast to the Kende reference which does not contain, for example, the amplification step. Indeed, the Kende reference does not describe the protocol as now recited in claim 11.

In addition, the McCafferty reference, whilst reporting the principle of using naïve phage display libraries to generate antibodies, does not teach or suggest the use of multiple carrier proteins to promote the selection of antibodies to the free form of an antigen molecule. Therefore, it is clear that the claims, as amended herein, are not obvious over the combination of the Kende and McCafferty references.

In view of the foregoing, Applicants respectfully request that the rejection of claims under 35 U.S.C. §103(a) be withdrawn.

### **III. Obviousness-Type Double Patenting**

Claims 1, 2, 6-12, 17-20, 24-29, 32, and 33 are provisionally rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims of co-pending application Serial No. 10/599,355 (hereinafter, the '355 application) and over claims of co-pending application Serial No. 11/568,673 (hereinafter, the '673 application). Claims 1, 2, 6-10, 17-20, 24-29, and 32 have been canceled herein and, thus, the rejections are moot with respect to

these claims. Applicants disagree with the rejections as they are applied to claims 11, 12, and 33, and respectfully request reconsideration because the claimed subject matter is not an obvious variant.

As a preliminary matter, as stated in § 804 of the MPEP:

If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

Thus, because the present application is the earlier-filed application of the three filed applications, and the provisional obviousness-type double patenting rejections should be the only remaining rejections in the present application, Applicants respectfully request that the rejections be withdrawn and the present application proceed to allowance.

To the extent that the provisional rejections are not the only rejections remaining, Applicants remind the Office that an obviousness-type double patenting rejection is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. §103. *In re Braithwaite*, 154 U.S.P.Q. 29, 34 (C.C.P.A. 1967) and *In re Longi*, 225 U.S.P.Q. 645, 648 n.4 (Fed. Cir. 1985). Thus, under the law, the pivotal question in an obviousness-type double patenting analysis is: Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent? *In re Vogel*, 164 U.S.P.Q. 619 (C.C.P.A. 1970). If the answer to this question is no, there can be no double patenting. In making this analysis, then, the proper inquiry is as taught in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). See, M.P.E.P. §804. No such inquiry has been made in regard to either the ‘355 or the ‘673 applications.

#### IV. Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants’ undersigned representative at 610.640.7859 to resolve any remaining issues.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

/Paul K. Legaard, Reg.# 38534/  
Paul K. Legaard, Ph.D.

Date: **19 August 2009**

Pepper Hamilton LLP  
400 Berwyn Park  
899 Cassatt Road  
Berwyn, PA 19312-1183

Telephone: 610.640.7859  
Facsimile: 267.430.7647